IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Tuan Bui, et al.
Appl. No.: 10/059,929
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Title: SYSTEM AND METHOD FOR OPERATING MEDICAL DEVICES
Art Unit: 3626
Examiner: Dilek B. Cobanoglu
Docket No.: EIS-5807 (112713-1098)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT OF JAMES MARTUCCI UNDER 37 C.F.R. § 1.131

Sir:

I, James Martucci, being duly sworn, hereby state:

1. I am one of the named inventors of the subject matter claimed in the above-identified patent application and am familiar with the inventions disclosed therein.

2. I conceived of the inventions of claims 1 to 191 in this country at least as early as November 30, 2001, as evidenced by a memorandum which I helped draft, a copy of which is attached as Exhibit A.

3. On December 3, 2001, I was copied on correspondence between Tuan Bui, a named inventor of the above-identified patent application, and our attorneys regarding the preparation and the subject matter of the above-identified patent application.

4. On or about December 9, 2001, I prepared comments regarding the preparation and the subject matter of the above-identified patent application.

5. On December 11, 2001, I forwarded my comments regarding the preparation and the subject matter of the above-identified patent application to my attorney for review.

6. On December 14, 2001, I met with my attorneys to discuss the preparation and the subject matter of the above-identified patent application.

7. I received a draft of the above-identified patent application from my attorneys on or about January 3, 2002.

8. I reviewed the draft patent application and provided my attorneys with my comments regarding same on January 14, 2001.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further, I acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issuing thereon.

FURTHER AFFIANT SAYETH NOT:

Signature _____ Date Signed 2/23/07

Name: James Martucci

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60048

State of IL)
) SS.
County of Lake)

On this 23 day of February, 2007, before me, a notary public, in and for the aforementioned state and county, personally appeared the person whose name is subscribed to the foregoing instrument, and executed the foregoing instrument in my presence for the purpose contained therein, by signing his name hereto.

IN WITNESS WHEREOF, I hereto set my hand and official seal.

Date: 2/23/2007 Kori R Caya
Notary Public

My Commission Expires: 6/14/10

OFFICIAL SEAL
KORI R CAYA
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:06/14/10

Exhibit A

Baxter

To: Fran Kowalik, Esq.
From: Tuan Bui & Jim Martucci
Subject: Detailed Description of Method to Program a Medical Device in a Network
Date: November 30, 2001

This document will describe alternative methods of programming a medical device within a computer network structure.

Background

The use of medical devices at the patient point of care (POC) has historically been accomplished using manual data management processes, (i.e., programming the device to the appropriate settings for a specific use, recording the output data and alarm conditions generated during routine use of the device on a patient) – via pen and paper data collection. The advent of wired computer networks in the early 1960s and the subsequent implementation of computer network standards such as Ethernet in the 1970s resulted in the growing use of computers to automate manual processes such as described above. However, medical institutions do not typically utilize such networks to the extent of including the point of care, i.e., the use of Ethernet at the patient bedside occurs is less than 10% in US hospitals (although the network is very commonly wired to the nursing station location). Possible reasons for the lack of connection to POC are: 1) the completion of the network to the POC in existing hospital facilities was cumbersome and costly 2) the presence of the wired network at POC may not have been worthwhile until medical instruments that can use those networks became available, 3) There are no standard communication protocols to enable instruments to easily communicate (although a great deal of effort has been focused on IEE 1073 and HL7, for example) and 4) there may be a multiplicity of different devices at the POC and these devices need to roam or move with the patient making the use of a wired solution difficult.

Starting in the 1980's the use of wireless computer networks, both proprietary (such as Proxim) and open (such as IEEE 802.11 "wireless Ethernet") enabled hospitals to use medical devices on patients and connect their input and output data via a wireless technology. This allowed hospitals to workaround issues 1-4 above because the network was relatively easy to install, devices were becoming available, the standard was Ethernet and the devices could roam.

Method for Programming Medical Devices, Including Infusion Pumps

Normally, the data set for programming a medical device, such as an infusion pump, originates with the physician order for a drug, which is captured in the database of the hospital pharmacy system. There may be exceptions such as emergency situations, or the use of an alternate site infusion center, but in the hospital environment, the pharmacy database is the key source of data. Today, the transfer of information from various aspect of the patient care, from order entry through the pharmacy to the programming of an infusion pump, is done manually: The process of generating a prescription label from the pharmacy system is done manually, and the clinician

manually programs that prescription data set into an infusion pump and manually captures the delivery history from the infusion pump to a medication administration record.

This invention proposes to program the medical device directly from the pharmacy database using a wireless computer network, including handheld devices at the POC to direct the process. It is integrated with a bar coding system to automatically verify the correct patient and prescription information as outlined below. The following is an outline:

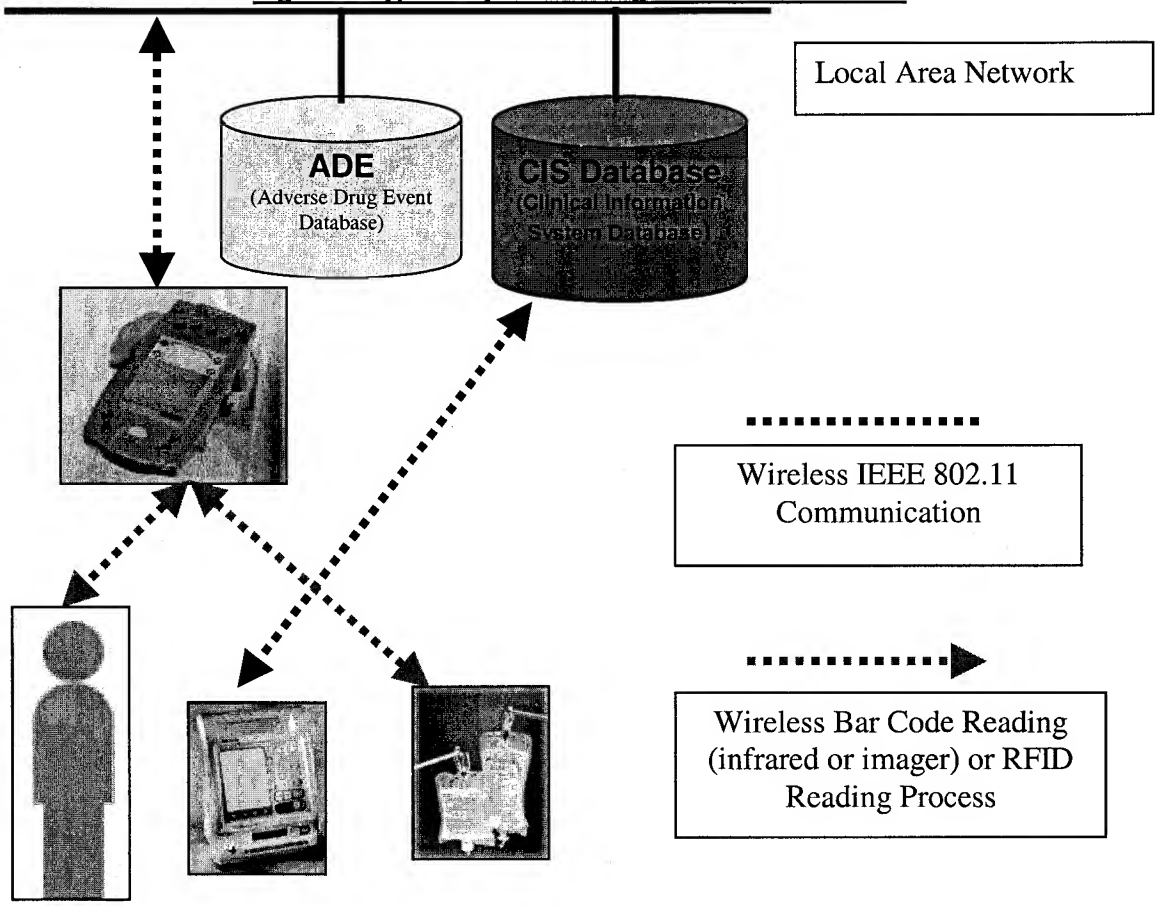
- **Option 1: Set Infusion Parameters Automatically**
- Scan patient
- Scan bag
- Scan pump
- If the patient bag and pump match, the system automatically uploads infusion parameters from pharmacy system (CIS Database in Figure 1 below) to infusion pump.

- **Option 2: Alternative Scheme to Set Infusion Parameters Manually**
- Nurse programs the pump manually.
- Prescription data is transmitted to the network from the pump via the wireless network
- Prescription data is checked against the order in the database
- CIS database sends a real-time warning to the PDA if there was a wrong entry
- System provides real-time tracking of flow rate and operating conditions of infusion pump. Alarm conditions are communicated to PDA from CIS database based on assigned patients.
- **Additional Feature of Tracking Clinical Documentation for Infusion Flow Rate Changes**
- Nurse scans bag.
- Nurse enters flow rate changes in the PDA (for mandatory documentation.
- Information is automatically sent to the CIS database in pharmacy for production scheduling updates.

The following is an outline of the clinical verifications that occur as a result of these steps.

- **Scan pump barcode**
- Identifies pump
- **Scan patient barcode**
- Verify ***RIGHT*** patient
- **Scan bag barcode**
- Verify ***RIGHT*** bag
- Verify in real-time whether order is still active
- Verify ***RIGHT*** start time
- Verify ***RIGHT*** bag sequence
- Clinical alerts, pre/post-admin actions

Figure I: Typical System Configuration for Invention



The following are potential inventive claims to support the invention. These proposed claims outline some alternatives that may not be described in detail above, but should be self –evident based on the background description.

CIS Server directly programs medical device

1) A method to control the delivery of medical treatment to a patient from a medical device, comprising of:

- Storing the medical treatment data in the first processor (medical treatment data = patient identification data, medication data, medical device operating parameters)
- Inputting patient identification data from a first source into the second processor.
- Inputting medication identification data from a second source into the second processor. Medication data include patient identification data.
- Verifying that the patient identification data from the first source matches with the patient identification data from the medication data.

- Communicating the medication data and the patient identification data from the second processor to the first processor.

- Comparing the communicated patient identification data with the stored data in the first processor (using the first processor?).

- Communicating the medical device operating parameters to the medical device from the first processor and programming the medical device according to the communicated operating parameters.

2) The method of claim 1 further comprising the steps of communicating the medical device operating parameters to the second processor.

CIS server directly programs medical device and user confirms

3) A method to control the delivery of medical treatment to a patient from a medical device, comprising of:

- Storing the medical treatment data in the first processor (medical treatment data = patient identification data, medication data, medical device operating parameters)

- Inputting patient identification data from a first source into the second processor.

- Inputting medication identification data from a second source into the second processor. Medication data include patient identification data.

- Verifying that the patient identification data from the first source matches with the patient identification data from the medication data

- Communicating the medication data and the patient identification data from the second processor to the first processor

- Comparing the communicated patient identification data with the stored data in the first processor (using the first processor?).

- Communicating the medical device operating parameters to the second processor.

- Confirmation of the medical device operating parameters on the second processor.

- Communicating the confirmation to the first processor.

- Communicating the confirmed medical treatment data from the first processor to the medical device and programming the medical device according to the communicated operating parameters

4) The method of claim 3 further comprising the steps of:

Communicating from the medical device to the second processor to acknowledge the completion of the programming of the medical device according to the communicated operating parameters

POC device programs medical device from bar code and CIS server confirms
5) A method to control the delivery of medical treatment to a patient from a medical device, comprising of:

- Storing the medical treatment data in the first processor (medical treatment data = patient identification data, medication data, medical device operating parameters)
- Inputting patient identification data from a first source into the second processor.
- Inputting medication identification data and medical device operating parameters from a second source (via bar code, or RFID, or magnetic stripe, or OCR) into the second processor. Medication data include patient identification data.
- Verifying that the patient identification data from the first source matches with the patient identification data from the medication data
- Communicating the medication data, the medical device operating parameters and the patient identification data from the second processor to the first processor.
- Comparing the communicated patient identification and medical device operating parameters data with the stored data in the first processor to confirm its' continued validity for patient care.
- (Optional) Communicating the medical device operating parameters to the second processor.
- (Optional) Confirmation of the medical device operating parameters on the second processor.
- (Optional) Communicating the confirmation to the first processor.
- Communicating the confirmed medical treatment data from the first processor to the medical device and programming the medical device according to the confirmed operating parameters

Medical device is POC device- no second processor
6) A method to control the delivery of medical treatment to a patient from a medical device, comprising of:

- Storing the medical treatment data in the first processor (medical treatment data = patient identification data, medication data, medical device operating parameters)

- Inputting patient identification data from a first source directly into the medical device (via bar code, or RFID, or magnetic stripe, or OCR).

- Inputting medication identification data and medical device operating parameters from a second source (via bar code, or RFID, or magnetic stripe, or OCR) directly into the medical device. Medication data include patient identification data.

- Verifying that the patient identification data from the first source matches with the patient identification data from the medication data

- Communicating the medication data, the medical device operating parameters and the patient identification data from the medical device to the first processor.

- Comparing the communicated patient identification and medical device operating parameters data with the stored data in the first processor to confirm its' continued validity for patient care.

- (Optional) Communicating the medical device operating parameters to the medical device.

- (Optional) Confirmation of the medical device operating parameters on the medical device.

- (Optional) Communicating the confirmation to the first processor.

- Communicating the confirmed medical treatment data from the first processor to the medical device and programming the medical device according to the confirmed operating parameters